



(Site Reported)

**Adverse Event Expedited Report**

Run Date : 02/25/2009 8:34:25 AM

**Protocol Number :** 7627      **CTC Version :** CTCAE v3.0      **Principal Investigator :**  
**Title :** A Phase II Study of GW 786034 (Pazopanib) in Advanced Thyroid Cancer  
**Institution :** Mayo Clinic Rochester      **Report Type :**      **Ticket #:**      **Amendment #:**  
**Created Date :** 02/25/2009

**Reporter Information**

**Reporter Name :** Robbin Peterson  
**Phone :** 507-776-3234      **Fax :** 507-999-9999      **Email :** peterson.robbin@mayo.edu  
**Submitter Name :** Robbin Peterson  
**Phone :** 507-776-3234      **Fax :** 507-999-9999      **Email :** peterson.robbin@mayo.edu  
**Physician Name :** Robbin Peterson  
**Phone :** 507-776-3234      **Fax :**      **Email :** peterson.robbin@mayo.edu

**Patient Information**

**Patient ID :** ex132929      **Birth Date :** 02/ 12/ 1941      **Gender :** Male  
**Race :** White      **Ethnicity :** Not Hispanic or Latino  
**Height(Centimeter ) :** 173      **Weight(Kilogram ) :** 67      **Body Surface Area :** 1. 794  
**Baseline performance status at initiation of protocol - ECOG/Zubrod scale :** 1 = Symptomatic, fully ambulatory  
**Disease Name :** Hurthle cell neoplasm (thyroid)  
**Disease Name Not Listed :**  
**Primary Site of Disease :** Thyroid  
**Date of Initial Diagnosis :** 07/1996

**Course Information**

**Treatment Assignment Code :** TAC 1  
**Description :** Cycle = 28 days: GW786034:  
800mg PO QD  
**Start date of first course :** 11/14/2008  
**Start date of course associated with Expedited Report :** 01/23/2009  
**Start date of primary AE :** 02/14/2009  
**End date of primary AE :** 02/19/2009  
**Course Number on which event(s) occurred :** 3  
**Total number of courses to date :** 3  
**Was Investigational Agent(s) administered on this protocol?:** Yes

**Description of Event**

**Description and Treatment of Event :** 3-4 day history of  
headache, vomiting started 2/17/09  
and found to have an intracranial  
bleed.  
**Present Status :** Not recovered/Not resolved      **Date of Recovery or Death :**  
**Retreated :** No  
**Removed from Protocol Treatment (to date) :** No      **Date Removed from Protocol Treatment :**  
**Cause of Death :**  
**Death Date :**      **Autopsy Performed :** No



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Therapy	Therapy Start Date	Therapy End Date	Comments	Chemotherapy Agents
Surgery	07//1996	07//1996	total thyroidectomy	
Surgery	07//2003	07//2003	radical neck dissection	
Surgery	09//2007	09//2007	thoracic laminectomy	
Surgery	02//2006	02//2006	neck mass resection	
Surgery	06//2007	06//2007	lt sternocleidomastoid resection	
Surgery	09//2008	09//2008	partial corpectomy T6	
Radiation Therapy	12//2007	12//2007	cyberknife	
Radiation Therapy	06//2006	06//2006	spine	
Image Directed Local Therapy	07//1996	07//1996	I131	
Hormonal Therapy	07//2003	07//2003	I131	



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**Protocol Agents**

Treatment Assignment Code :						
Agent	Total Dose Administered this Course	Last Administered Date	Comments	Agent Adjustment	Agent Delayed	Delay
GW786034 (pazopanib)	21600mg	02/18/2009				

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**Adverse Events (CTCAE)**

CTCAE CATEGORY	Adverse Event	Grade	Hospitalization or Prolongation of Hospitalization	Start Date	End Date	Is Primary AE?	Comments
PAIN	Pain - Head/headache	3: Severe	1: Yes	02/14/2009	02/19/2009	Yes	
HEMORRHAGE/BLEEDING	Hemorrhage, CNS	2: Moderate	1: Yes	02/14/2009		No	

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**Attribution for Adverse Events**

Attribute to	3: Severe	Pain - Head/headache
Course		
GW786034 (pazopanib)	3: Possible	
Disease		
Hurthle cell neoplasm (thyroid)	2: Unlikely	
Attribute to	2: Moderate	Hemorrhage, CNS
Course		
GW786034 (pazopanib)	3: Possible	
Disease		
Hurthle cell neoplasm (thyroid)	3: Possible	

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